NOTICES OF SUPPLEMENTAL PROPOSED RULEMAKING

After an agency has filed a Notice of Proposed Rulemaking with the Secretary of State's Office for *Register* publication and the agency decides to make substantial changes to the rule after it is proposed, the agency must prepare a Notice of Supplemental Proposed Rulemaking for submission to the Office, and the Secretary of State shall publish the Notice under the Administrative Procedure Act (A.R.S. § 41-1001 et seq.). Publication of the Notice of Supplemental Proposed Rulemaking shall appear in the *Register* before holding any oral proceedings (A.R.S. § 41-1022).

NOTICE OF SUPPLEMENTAL PROPOSED RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

[R08-98]

PREAMBLE

1. *Register* citation and date for the Notice of Rulemaking Docket Opening and Notice of Proposed Rulemaking:

Notice of Rulemaking Docket Opening: 13 A.A.R. 3155, September 14, 2007

Notice of Proposed Rulemaking: 13 A.A.R. 4362, December 14, 2007

Notice of Supplemental Proposed Rulemaking: 14 A.A.R. 494, February 22, 2008

2. Sections Affected / Rulemaking Action

R4-23-110	Amend
Article 5	New Article
R4-23-501	New Section
R4-23-502	New Section
R4-23-503	New Section
R4-23-504	New Section
R4-23-505	New Section

3. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rule is implementing (specific):

Authorizing statutes: A.R.S. §§ 32-1904(A)(1) and 36-2602

Implementing statutes: A.R.S. §§ 36-2603, 36-2604, 36-2605, 36-2606, 36-2607, 36-2608, 36-2609, and 36-2610

4. The name and address of agency personnel with whom persons may communicate regarding the rule:

Name: Dean Wright, Compliance Officer

Address: Board of Pharmacy
1700 W. Washington St., Suite 250
Phoenix, AZ 85007

Telephone: (602) 771-2727

Fax: (602) 771-2749

E-mail: dwright@azpharmacy.gov

5. An explanation of the rule, including the agency's reasons for initiating the rule:

During the 48th Legislative Session, the Legislature passed H.B. 2136. The bill requires the Board to adopt rules establishing a controlled substances prescription monitoring program that includes a computerized central database tracking system to track the prescribing, dispensing, and consumption of Schedule II, III, and IV controlled substances that are dispensed by a medical practitioner or pharmacy that holds a valid license or permit issued under A.R.S. Title 32. Any necessary new definitions will be placed in R4-23-110 (Definitions). The new rules will be placed in a new Article 5 (Controlled Substances Prescription Monitoring Program) with new Sections for: program registration, requirements for data format and transmission, access to program data, computerized central database tracking system task force, and reports. The rules will include format, style, and grammar necessary to comply with the current rules of the Secretary of State and Governor's Regulatory Review Council.

The Board believes that approval of the rules benefits the public and the pharmacy and medical communities by establishing a central repository of all prescriptions dispensed for Schedule II, III, and IV controlled substances in Arizona. The program will improve the state's ability to identify controlled substance abusers or misusers and refer

them to treatment, and to identify and stop diversion of prescription drugs in an efficient and cost effective manner that will not impede the appropriate medical utilization of licit controlled substances.

6. An explanation of the substantial change, which resulted in this supplemental notice:

Representatives of the Arizona Veterinary Medical Association (AVMA) came to Hal Wand the Board's Executive Director after the Notice of Supplemental Proposed Rulemaking was published on February 22, 2008. The AVMA expressed concerns with the Prescription Monitoring Program and its rules as it relates to veterinary medical practitioners. During the public hearing on the Notice of Supplemental Proposed Rulemaking held on March 24, 2008, the AVMA asked the Board to delay the start of data collection from veterinarians for one year to allow the veterinarians more time to prepare. The AVMA states that the majority of veterinarians do not have computer systems for patient records and they do not collect certain owner information (date of birth and gender) that will be required by the new rules. The AVMA also feels that having to report the data weekly is onerous, as the number of veterinary drugs and prescriptions is very small (only five or six drugs) compared to medical practitioners and pharmacies. The AVMA is asking that veterinarians be allowed to report on a monthly basis. Reporting on a monthly basis would reduce the economic impact on veterinarians and their staff and still provide the small quantity of veterinarian prescription data in a reasonable time.

Based on the comments from the AVMA, the Board expressed its desire to work with the AVMA to help mitigate the program's impact on veterinarians by delaying the collection of data from veterinarians and other medical practitioners for a year. The Board agrees that since veterinarians use so few controlled drugs and dispense a limited quantity of prescriptions for those drugs, it is reasonable to have veterinarians report their dispensed prescription data on a monthly schedule instead of weekly. Section R4-23-502 is amended by adding the sentence: "The Board may approve a less frequent reporting period." to the end of subsection (E). The Board will then be able to approve a request to report prescription monitoring program data using a less frequent reporting period on a case-by-case basis. The Board feels that this substantive change will allow the Board to address specific issues from the regulated public regarding the collection of prescription monitoring program data without compromising the public health and safety.

7. A reference to any study relevant to the rule that the agency reviewed and proposes either to rely on or not to rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

The agency did not review or rely on any study relevant to the rule.

8. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

9. The summary of the economic, small business, and consumer impact:

The proposed rules will impact the Board, medical practitioners, pharmacies, pharmacists, and the public. The proposed rule's impact on the Board will be the usual rulemaking-related costs, which are minimal. The Board estimates the cost of the program will be from $200,000 to $400,000 per year. The costs of the program will be borne by the Board through an annual appropriation of $395,795 from the Board's Pharmacy Fund. The Board will seek additional federal grants when available to help pay the costs of the program.

The Board estimates the proposed rules will have minimal to moderate economic impact on pharmacies or pharmacists. The cost to pharmacies will be to prepare and transmit the prescription data to the Board. The majority of pharmacies already transmit similar data in other states with a monitoring program. The few Arizona pharmacies that do not have a computer will be required to transmit the data through use of a universal claim form. There will be a cost in man-hours to manually prepare and transmit the data. The Board estimates this cost will be from $0 to $10 per day equaling an annual additional cost of from $0 to $2,600.

The Board estimates the proposed rules will have minimal to moderate economic impact on medical practitioners. Those medical practitioners who dispense Schedule II, III, and IV controlled substances to patients will be required to transmit prescription data to the Board. Those medical practitioners without computers will be required to manually transmit the data, which will require a staff person to complete a type of universal claim form. There will be a cost in man-hours to prepare and transmit the data. The Board estimates this additional cost may apply to approximately 2,000 of the estimated 24,000 medical practitioners licensed to practice medicine in Arizona. The Board estimates an average medical practice will need an additional one to two man-hours to process the prescription data at a cost of from $0 to $25 per day, equaling an additional annual cost of from $0 to $6,500.

The public, Board, and pharmacists benefit from rules that are clear, concise, and understandable. The Board rules benefit the public and the pharmacy and medical communities by establishing a central repository of all prescriptions dispensed for Schedule II, III, and IV controlled substances in Arizona. The program will improve the state's ability to identify controlled substance abusers or misusers and refer them to treatment, and to identify and stop diversion of prescription drugs in an efficient and cost effective manner that will not impede the appropriate medical utilization of licit controlled substances.

10. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:

Name: Dean Wright, Compliance Officer

Address:	Board of Pharmacy 1700 W. Washington St., Suite 250 Phoenix, AZ 85007
Telephone:	(602) 771-2727
Fax:	(602) 771-2749
E-mail:	dwright@azpharmacy.gov

11. The time, place, and nature of the proceedings for the making, amendment, or repeal of the rules or, if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rules:

Comments may be written or presented orally. Written comments must be received by 5:00 p.m., Monday, May 19, 2008. An oral proceeding is scheduled for:

Date:	May 19, 2008
Time:	10:00 a.m.
Location:	1700 W. Washington St., Suite 250 Phoenix, AZ 85007
Nature:	Public Hearing
Close of Record:	5:00 p.m. on May 19, 2008

A person may request information about the oral proceeding by contacting the person listed above.

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable

13. Any material incorporated by reference and its location in the rules:

None

14. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 1. ADMINISTRATION

Section
R4-23-110. Definitions

ARTICLE 5. ~~RECODIFIED~~ CONTROLLED SUBSTANCES PRESCRIPTION MONITORING PROGRAM

Section
R4-23-501. ~~Recodified~~ Controlled Substances Prescription Monitoring Program Registration
R4-23-502. ~~Recodified~~ Requirements for Data Format and Transmission
R4-23-503. ~~Repealed~~ Access to Controlled Substances Prescription Monitoring Program Data
R4-23-504. ~~Repealed~~ Computerized Central Database Tracking System Task Force
R4-23-505. ~~Repealed~~ Reports

ARTICLE 1. ADMINISTRATION

R4-23-110. Definitions

In addition to definitions in A.R.S. § 32-1901, the following definitions apply to 4 A.A.C. 23:

"Active ingredient" No change

"Alternate physician" No change

"Approved course in pharmacy law" No change

"Approved Provider" No change

"Authentication of product history" No change

"Automated storage and distribution system" No change

"Batch" No change

"Beyond-use date" No change

"Biological safety cabinet" No change
"Care-giver" No change
"Community pharmacy" No change
"Component" No change
"Computer system" No change
"Computer system audit" No change
"Contact hour" No change
"Container" No change
"Continuing education" No change
"Continuing education activity" No change
"Continuing education unit" or "CEU" No change
"Correctional facility" No change
"CRT" No change
"CSPMP" means the Controlled Substances Prescription Monitoring Program established under A.R.S. Title 36, Chapter 28.
"Current good compounding practices" No change
"Current good manufacturing practice" No change
"Cytotoxic" No change
"Day" No change
"DEA" No change
"Delinquent license" No change
"Dietary supplement" No change
"Digital signature" No change
"Dispensing pharmacist" No change
"Drug sample" No change
"Drug therapy management" No change
"Electronic signature" No change
"Eligible patient" No change
"Extreme emergency" No change
"FDA" No change
"Immediate notice" No change
"Inactive ingredient" No change
"Internal test assessment" No change
"ISO Class 5 environment" No change
"ISO Class 7 environment" No change
"Limited-service correctional pharmacy" No change
"Limited-service long-term care pharmacy" No change
"Limited-service mail-order pharmacy" No change
"Limited-service nuclear pharmacy" No change
"Limited-service pharmacy permittee" No change
"Limited-service sterile pharmaceutical products pharmacy" No change
"Long-term care consultant pharmacist" No change
"Long-term care facility" or "LTCF" No change
"Lot" No change
"Lot number" or "control number" No change
"Materials approval unit" No change
"Mechanical counting device for a drug in solid, oral dosage form" No change
"Mechanical storage and counting device for a drug in solid, oral dosage form" No change

"Mediated instruction" No change

"MPJE" No change

"NABP" No change

"NABPLEX" No change

"NAPLEX" No change

"Order" No change

"Other designated personnel" No change

"Outpatient" No change

"Outpatient setting" No change

"Patient profile" No change

"Pharmaceutical patient care services" No change

"Pharmaceutical product" No change

"Pharmacist-administered immunizations training program" No change

"Pharmacy counter working area" No change

"Pharmacy law continuing education" No change

"Pharmacy permittee" No change

"Prepackaged drug" No change

"Prep area" No change

"Proprietor" No change

"Provider pharmacy" No change

"Radiopharmaceutical" No change

"Radiopharmaceutical quality assurance" No change

"Radiopharmaceutical services" No change

"Red C stamp" No change

"Refill" No change

"Remodel" No change

"Remote drug storage area" No change

"Resident" No change

"Responsible person" No change

"Score transfer" No change

"Security ~~paper~~ features" means the attributes incorporated into the paper of a prescription order, referenced in A.R.S. § 32-1968(A)(4), that ~~is~~ are approved by the Board or its staff and that includes one or more of the following features that attempt to prevent duplication or aid the authentication of a paper document: laid lines, enhanced laid lines, thermochromic ink, artificial watermark, fluorescent ink, chemical void, persistent void, penetrating numbers, high-resolution border, high-resolution latent images, micro-printing, prismatic printing, embossed images, abrasion ink, holograms, and foil stamping.

"Shared order filling" No change

"Shared order processing" No change

"Shared services" No change

"Sight-readable" No change

"Single-drug audit" No change

"Single-drug usage report" No change

"Standard-risk sterile pharmaceutical product" No change

"Sterile pharmaceutical product" No change

"Strength" No change

"Substantial-risk sterile pharmaceutical product" No change

"Supervision" No change

"Supervisory physician" No change

"Supplying" No change

"Support personnel" No change

"Transfill" No change

"Verified signature" or "signature verifying" No change

"Wholesale distribution" No change

"Wholesale distributor" No change

ARTICLE 5. ~~RECODIFIED~~ CONTROLLED SUBSTANCES PRESCRIPTION MONITORING PROGRAM

R4-23-501. ~~Recodified~~ Controlled Substances Prescription Monitoring Program Registration

A. Under A.R.S. § 36-2606, a medical practitioner who is issued a license under A.R.S. Title 32, Chapter 7, 11, 13, 14, 15, 16, 17, 21, 25, or 29 and possesses a current DEA registration under the Federal Controlled Substances Act shall have a current CSPMP registration issued by the Board.

B. Application. To obtain a CSPMP registration, a person shall submit a completed application on a form furnished by the Board that includes:

1. Applicant's name, address, mailing address, if different, e-mail address, telephone number, facsimile number, license number issued under A.R.S. Title 32, Chapter 7, 11, 13, 14, 15, 16, 17, 21, 25, or 29, and DEA registration number;
2. Whether the applicant's license and DEA registration listed in subsection (B)(1) are current and in good standing, and if not, the status of the license and registration; and
3. Date signed and applicant's verified signature.

C. Registration. Within seven business days of receipt of a completed application specified in subsection (B), the Board office shall determine whether an application is complete. If the application is complete, the Board office shall issue a registration number and mail a current renewal receipt to the applicant. If the application is incomplete, the Board office shall issue a notice of incompleteness. An applicant with an incomplete application shall comply with the requirements of R4-23-202(F)(2) and (3).

D. Registration renewal. As specified in A.R.S. § 36-2606(C), the Board shall automatically suspend the registration of any registrant that fails to renew the registration on or before May 1 of the year in which the renewal is due. The Board shall vacate a suspension if the registrant submits a renewal application. A suspended registrant is prohibited from accessing information in the prescription monitoring program database.

E. Pharmacy registration and renewal. Each pharmacy with a current Board-issued pharmacy permit and a current DEA registration is automatically registered in the CSPMP. Existing pharmacy permittees who possess a current DEA registration will receive a registration receipt before the implementation date of the CSPMP. For pharmacy permits issued on or after the CSPMP implementation date, the Board will issue a registration receipt when issuing the pharmacy's permit. Each pharmacy shall renew the CSPMP registration on or before May 1 of the year in which the renewal is due. The Board shall automatically suspend the registration of any registrant that fails to renew the registration on or before the date on which the renewal is due. The Board shall vacate a suspension if the registrant submits a renewal application. A suspended registrant is prohibited from accessing information in the prescription monitoring program database.

F. CSPMP database access. A medical practitioner or pharmacy that chooses to use the CSPMP database shall request a user name and password in writing from the CSPMP Director. Upon receipt of the request, the CSPMP Director or designee shall issue a user name and password provided the medical practitioner or pharmacy is in compliance with the registration requirements of this Section.

R4-23-502. ~~Recodified~~ Requirements for Data Format and Transmission

A. Each dispenser shall submit to the Board or its designee by electronic means information regarding each prescription dispensed for a controlled substance listed in Schedules II, III, and IV of A.R.S. Title 36, Chapter 27, the Arizona Uniform Controlled Substances Act. The information reported shall conform to the August 31, 2005 Version 003, Release 000 *ASAP Rules-based Standard Implementation Guide for Prescription Monitoring Programs* published by the American Society for Automation in Pharmacy as specified in A.R.S. § 36-2608(B). The information submitted for each prescription shall include:

1. The name, address, telephone number, prescription number, and DEA registration number of the dispenser;
2. The name, address, gender, date of birth, and telephone number of the person or, if for an animal, the owner of the animal for whom the prescription is written;
3. The quantity and National Drug Code (NDC) number of the Schedule II, III, or IV controlled substance dispensed;
4. The date the prescription was dispensed;
5. The number of refills, if any, authorized by the medical practitioner;
6. The date the prescription was issued;
7. The method of payment identified as cash or third party; and
8. Whether the prescription is new or a refill.

B. A dispenser shall submit the required information electronically unless the Board approves a waiver as specified in subsection (D).

C. A dispenser's electronic data transfer equipment including hardware, software, and internet connections shall meet the privacy and security standards of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 and A.R.S. § 12-2292, in addition to common internet industry standards for privacy and security. A dispenser shall ensure that each electronic transmission meets the following data protection requirements:
1. Data shall be at least 128-bit encryption in transmission and at rest; and
2. Data shall be transmitted via secure e-mail, telephone modem, diskette, CD-ROM, tape, secure File Transfer Protocol (FTP), Virtual Private Network (VPN), or other Board-approved media.

D. A dispenser who does not have an automated recordkeeping system capable of producing an electronic report in the Board-established format may request a waiver from electronic reporting by submitting a written request to the Board. The Board shall grant the request if the dispenser agrees in writing to report the data by submitting a completed universal claim form supplied by the Board or its designee.

E. A dispenser shall report by close of business on each Friday the required information for the previous week, Sunday through Saturday. If a Friday falls on a state holiday, the dispenser shall report the information on the following business day. The Board may approve a less frequent reporting period.

R4-23-503. ~~Repealed~~ Access to Controlled Substances Prescription Monitoring Program Data

A. Except as provided in A.R.S. §§ 36-2604(B) and (C) and this Section, prescription information submitted to the Board or its designee is confidential and is not subject to public inspection.

B. The Board or its designee shall review the prescription information collected under A.R.S. Title 36, Chapter 28 and R4-23-502. If the Board or its designee has reason to believe an act of unprofessional or illegal conduct has occurred, the Board or its designee shall notify the appropriate professional licensing board or law enforcement or criminal justice agency and provide the prescription information required for an investigation.

C. The Board or its designee is authorized to release data collected by the program to the following:
1. A person who is authorized to prescribe or dispense a controlled substance to assist that person to provide medical or pharmaceutical care to a patient or to evaluate a patient;
2. An individual who requests the individual's own controlled substance prescription information under A.R.S. § 12-2293;
3. A professional licensing board established under A.R.S. Title 32, Chapter 7, 11, 13, 14, 15, 16, 17, 18, 21, 25, or 26. Except as required under subsection (B), the Board or its designee shall provide this information only if the requesting board states in writing that the information is necessary for an open investigation or complaint;
4. A local, state, or federal law enforcement or criminal justice agency. Except as required under subsection (B), the Board or its designee shall provide this information only if the requesting agency states in writing that the information is necessary for an open investigation or complaint;
5. The Arizona Health Care Cost Containment System Administration regarding persons who are receiving services under A.R.S. Title 36, Chapter 29. Except as required under subsection (B), the Board or its designee shall provide this information only if the Administration states in writing that the information is necessary for an open investigation or complaint;
6. A person serving a lawful order of a court of competent jurisdiction; and
7. The Board staff for purposes of administration and enforcement of A.R.S. Title 36, Chapter 28 and this Article.

D. The Board or its designee may provide data to public or private entities for statistical, research, or educational purposes after removing information that could be used to identify individual patients or persons who received prescriptions from dispensers.

R4-23-504. ~~Repealed~~ Computerized Central Database Tracking System Task Force

A. The Board shall appoint a task force to help it administer the computerized central database tracking system as specified in A.R.S. § 36-2603.

B. The Task Force shall meet at least once each year and at the call of the chairperson to establish the procedures and conditions relating to the release of prescription information specified in A.R.S. § 36-2604 and R4-23-503.

C. The Task Force shall determine:
1. The information to be screened;
2. The frequency and thresholds for screening; and
3. The parameters for using the information to notify medical practitioners, patients, and pharmacies to educate and provide for patient management and treatment options.

D. The Board shall review and approve the procedures and conditions established by the Task Force as needed but at least once every calendar year.

R4-23-505. ~~Repealed~~ Reports

A. Before releasing prescription monitoring program data, the Board or its designee shall receive a written request for controlled substance prescription information.

B. A person authorized to access CSPMP data under R4-23-503(C)(1) through (6) shall submit a written request that:
1. Specifies the information requested for the report;
2. For a medical practitioner, provides a statement that the report's purpose is to provide medical or pharmaceutical care

to a patient or to evaluate a patient;

3. For an individual obtaining the individual's own controlled substance prescription information, provides a form of non-expired government-issued identification;
4. For a professional licensing board, states that the information is necessary for an open investigation or complaint;
5. For a local, state, or federal law enforcement or criminal justice agency, states that the information is necessary for an open investigation or complaint;
6. For the AHCCCS Administration, states that the information is necessary for an open investigation or complaint; and
7. For a person serving a lawful order of a court of competent jurisdiction, provides a copy of the court order.

C. The Board or its designee may provide reports through U.S. mail, other common carrier, facsimile, or secured electronic media or may allow reports to be picked up in-person at the Board office.